

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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BIOZONE LABORATORIES, INC.,	: Case No.:
	:
Plaintiff,	: COMPLAINT
	: JURY TRIAL DEMANDED
-against-	:
	:
	:
NEXT STEP LABORATORIES CORP. AND	:
RICHARD RIGG,	:
	:
Defendants.	:
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COMPLAINT FOR PATENT INFRINGEMENT

This is an action for patent infringement arising under the Patent Laws of the United States of America, 35 U.S.C. § 100 et seq. brought by Plaintiff BioZone Laboratories, Inc. (“BioZone” or “Plaintiff”) against Defendants Next Step Laboratories Corp. (“NSL”) and Richard Rigg (“Rigg”) (collectively, “Defendants”), alleging as follows:

PARTIES

1. Plaintiff BioZone Laboratories, Inc. is a California corporation with its principal place of business at 580 Garcia Avenue, Pittsburg, CA 94565.
2. Defendant Next Step Laboratories Corp. is a New York corporation with its principal place of business at 130-13 91st Avenue, Richmond Hill, NY 11418. Defendant has not designated an agent for service of process, and may be served at the above address.
3. Defendant Richard Rigg is the President and Chief Executive Officer of NSL having an address of 130-13 91st Avenue, Richmond Hill, NY 11418. Rigg may be served at this address.

BACKGROUND

4. BioZone is the assignee of all right, title, and interest in and to U.S. Patent No. 6,610,322 entitled “Self forming, thermodynamically stable liposomes and their applications” (“the ‘322 Patent,”” attached as Exhibit A), U.S. Patent No. 6,958,160 entitled “Self forming, thermodynamically stable liposomes and their applications” (“the ‘160 Patent,”” attached as Exhibit B), U.S. Patent No. 7,718,190 entitled “Self forming, thermodynamically stable liposomes and their applications” (“the ‘190 Patent,”” attached as Exhibit C), U.S. Patent No. 7,150,883 entitled “Patent for inventions covering Self forming, thermodynamically stable liposomes and their applications” (“the ‘883 Patent,”” attached as Exhibit D), U.S. Patent No. 6,495,596, entitled “Covering compounds and methods for inhibition of phospholipase A2 and cyclooxygenase-2” (“the ‘596 Patent,”” attached as Exhibit E), and U.S. Patent No. 6,998,421, entitled “Compounds and methods for inhibition of phospholipase A2 and cyclooxygenase - 2” (“the ‘421 Patent,”” attached as Exhibit F) (collectively, the “Patents-in-Suit”).

5. BioZone has the exclusive right to assert all causes of action arising under the Patents-in-Suit and the right to remedies for infringement thereof.

6. The Patents-in-Suit cover BioZone’s proprietary QuSome® and Inflacin® technologies.

7. Defendants admit that BioZone’s QuSome and Inflacin technologies are “patented” by BioZone.

8. Defendants have been aware of the Patents-in-Suit since their dates of issuance or since June 2005. Defendants are aware of their infringing activities as described herein.

Defendants’ Use of BioZone’s Patented QuSomes Technology

9. Defendants claim to offer a complete development platform of cosmetic ingredients and finished formulations supported with critical in vitro and clinical testing. Defendants offer active ingredients prepared in QuSomes, which Defendants admit is BioZone's patented technology.

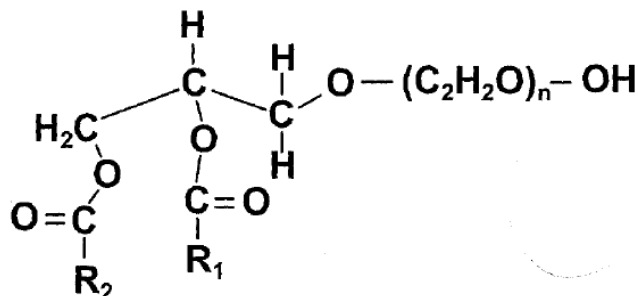
10. According to Defendants, QuSomes allow active ingredients to become more efficacious and less irritating, providing consumers with maximum product performance. Defendants state that it makes available QuSomes with active ingredients including salicylic acid, AHAs, peptides, vitamins, botanical extracts, and synthetic molecules. Defendants state that it develops custom QuSomes ingredients for specific customer needs.

11. According to Defendants, a key feature of QuSomes is the spontaneous formation upon addition of water, without standard heating, cooling and agitation methods, making it easier to encapsulate active ingredients, and achieving higher encapsulation of active ingredients.

12. According to Defendants, QuSomes can be used in higher concentrations. Defendants state that they have lower cost, offer enhanced encapsulation of the active ingredient, and offer improved active ingredient performance through highly effective delivery. Defendants state that QuSomes deliver a greater amount of the active ingredients to the skin as compared to conventional vehicles.

13. Defendants use PEG-12 Glyceryl Dimyristate, which is known under the International Nomenclature of Cosmetic Ingredients ("INCI") name of PEG-12 GDM, to make and offer QuSomes.

14. PEG-12 GDM is represented by the following formula, where R_1 and $R_2 = \text{CH}_3(\text{CH}_2)_{12}$ and $n=12$:



15. In the above formula for PEG-12 GDM, R_1 and R_2 are long chain fatty acids having fourteen carbons in length, with values of P_a , the packing parameter with respect to surface, of .853, and P_v , the packing parameter with respect to volume, of .889, and being a fluid at 25° Celsius.

16. PEG-12 GDM is used in products made and offered by Defendants, including but not limited to Qusome, Aqua-illum- Qusome, Benzoyl Peroxide Qusome, CA Qusome, Caffeine Qusome, CBD Qusome (3.8% CBD), CITRIC ACID Qusome, DHA 60% and Qusome, DRC Qusome, Gatuline Malakite Qusome, Glycolic Acid Qusome 45%, Glycolic Acid Qusome, JDC Qusome, Linefactor Qusome, MV Qusome, NS CS Qusome, NS Hair AA Qusome, NS Hexylrersorcinol Qusome, NS Hydroquinone Qusome, NS Sun Protect Qusome, NS White Qusome, NYDG Brightening Qusome, PhytoMoist Qusome, Qusome AA, Regu-Age Qusome, Retinol Qusome, Sal-Acid BG Qusome, Sal-Acid PD Qusome, Sal-GA Qusome, SkinBright Qusome 30%, Symwhite Qusome, Upregulex Qusome, Warming Qusome, Wild Yam/Black Cohosh Qusome, NS Calming Complex, NS Cooling Qusome, NS iRelief Qusome, NS iRestore, NS Lipolysis, NS Menthol Qusome, NS Multi Acid Qusome, NS Multiberry Extract, NS PhotoProtect, NS Relaxin, NS RepairEx, NS VeinEx, 2% Salicylic Acid Cleaner, 2% Salicylic Acid Lotion, Anti-Acne Facial Mask, Anti-Aging Serum, Peptide Qusome, Biobase SM, BBW Qusome, NS Skin Replacement Lipid (SRL), VeinEX, GR Anti Acne Facial Lotion, and GR Anti Acne Facial Cleanser (collectively, the “QuSomes Products”).

17. Making QuSomes Products entails combining an aqueous solution with PEG-12 GDM at a temperature above 25° Celsius, thereby spontaneously creating QuSomes, which are liposomes.

18. Evidence of Defendants' making, using, selling, offering for sale, or importing QuSomes Products is attached hereto as Exhibit G.

Defendants' Use of BioZone's Patented Inflacin Technology

19. According to Defendants, Inflacin is an anti-inflammatory molecule that blocks the phospholipase A₂ (PLA₂) enzyme in the inflammatory pathway, thus shutting down the inflammatory pathway which leads to redness and irritation.

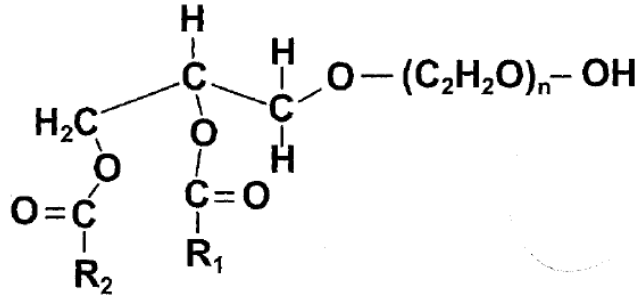
20. Inflacin is a lipid that has anti-inflammatory properties.

21. Defendants state that Inflacin is recommended for use in sensitive skin products, alpha and beta hydroxy products as well as anti-aging products, because inflammation is the precursor to aging. Defendants highly recommend Inflacin for all products targeting sensitive skin such as hypoallergenic products, as well as after-shave balms and products for post-waxing pain relief.

22. According to Defendants, Inflacin has features and benefits including that it acts as an anti-inflammatory, reduces redness, and is an anti-irritant.

23. Defendants use PEG-23 Glyceryl Distearate, which is known under the INCI name of PEG-23 GDS, to make and offer Inflacin.

24. PEG-23 GDS is represented by the following formula, where R₁ and R₂ = CH₃(CH₂)₁₆ and n=23:



25. In the above formula for PEG-23 GDS, R_1 and R_2 are long chain fatty acids having eighteen carbons in length, with values of P_a , the packing parameter with respect to surface, of .849, and P_v , the packing parameter with respect to volume, of .885, and being a fluid at 39.8° Celsius. As Defendants admit, PEG-23 GDS is characterized by the ability to inhibit biological activity of phospholipase A_2 .

26. PEG-23 GDS is used in products made and offered by Defendants, including but not limited to Inflacin, 2% Salicylic Acid Cleaner (Global), 2% Salicylic Acid Lotion (Global), GR Anti Acne Facial Lotion, and GR Anti Acne Facial Cleanser (collectively, the “Inflacin Products”). Inflacin Products include therapeutic agents.

27. Evidence of Defendants’ making, using, selling, offering for sale, or importing Inflacin Products is attached hereto as Exhibit G.

28. On information and belief, Defendant Rigg is personally involved in, and controls, the development, manufacture, offers for sale, sales, marketing, advertising and other activities relating to the QuSomes Products and Inflacin Products, including the wrongful acts described herein.

JURISDICTION AND VENUE

29. This action arises under the patent laws of the United States, Title 35 of the United States Code. Accordingly, this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

30. This Court has personal jurisdiction over Defendants because, among other reasons, Defendants have established minimum contacts with the forum state of New York.

31. Venue is proper in this District under 1400(b) because Defendants have committed acts of patent infringement in this District and has a regular and established place of business in this District located at 130-13 91st Avenue, Richmond Hill, NY 11418.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,610,322

32. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

33. On August 26, 2003, the United States Patent and Trademark Office issued the ‘322 Patent for inventions relating to self forming, thermodynamically stable liposomes and their applications. The embodiment of claim 1 recites a method of spontaneously preparing liposomes, the method consisting essentially of: providing an aqueous solution; providing one or more diacylglycerol-PEG lipids where the lipid or lipids have a P_a between about 0.84 and 0.88 and a P_v between about 0.88 and 0.93 and where P_a is the packing parameter with respect to surface and P_v is the packing parameter with respect to volume; and combining the lipid or lipids and the aqueous solution at a temperature above the melting point of the lipid or lipids.

34. Defendants have been and is now directly and indirectly infringing one or more claims of the ‘322 Patent, in this judicial District and elsewhere in the United States.

35. For example, Defendants directly infringe the ‘322 Patent, including but not limited to claim 1, by offering to sell the QuSomes Products, according to the claims of the ‘322 Patent.

36. Defendants also directly and indirectly infringe the '322 Patent, including but not limited to claim 1, to the extent Defendants may also be making, using, selling, or importing QuSomes Products.

37. Defendants have committed these acts of infringement without license or authorization.

38. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the '322 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

39. As a result of Defendants' infringement of the '322 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 6,958,160

40. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

41. On October 25, 2005, the United States Patent and Trademark Office issued the '160 Patent for inventions relating to self forming, thermodynamically stable liposomes and their applications. The embodiment of claim 1 recites a liposome comprising: one or more lipids where the total lipids have a P_a between about 0.84 and 0.88 and a P_v between about 0.88 and 0.93, where P_a is the packing parameter with respect to surface and P_v is the packing parameter with respect to volume, where one or more of the lipids is a diacylglycerol-PEG, where the melting point of the diacylglycerol-PEG is below about 40 degrees C, and where the acyl chains of the diacylglycerol-PEG are greater than or equal to 14 carbons in length.

42. Defendants have been and is now directly and indirectly infringing one or more claims of the '160 Patent, in this judicial District and elsewhere in the United States.

43. For example, Defendants directly infringe the '160 Patent, including but not limited to claim 1, by offering to sell the QuSomes Products, according to the claims of the '322 Patent.

44. Defendants also directly and indirectly infringe the '160 Patent, including but not limited to claim 1, to the extent Defendants may also be making, using, selling, or importing QuSomes Products.

45. Defendants have committed these acts of infringement without license or authorization.

46. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the '160 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

47. As a result of Defendants' infringement of the '160 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 7,718,190

48. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

49. On May 18, 2010, the United States Patent and Trademark Office issued the '190 Patent for inventions covering self forming, thermodynamically stable liposomes and their applications. The of claim 1 recites a composition for the preparation of a liposome, said composition comprising: an active compound, where the active compound is a protein, peptide,

nucleic acid, agent for treating a neoplasm, agent for treating inflammation, agent for treating an infection, agent for treating a gastrointestinal disease, agent for treating an immunological disease, agent for treating a skin diseases or an eye disease, agent use in diagnosing disease, nutrient, agent for treating a blood disease, agent for treating a metabolic disease, agent for treating a cardiovascular disease, agent for treating a renal disease, agent for treating a genitourinary disease, agent for treating a respiratory disease or agent for treating a central nervous system disease; and one or more lipids selected from the group consisting of PEG-12 glycerol dioleate (GDO), PEG-12 glycerol dimyristate (GDM), PEG-23 glycerol dipalmitate (GDP), PEG-12 glycerol distearate (GDS), and PEG-23 GDS, where the number after “PEG” indicates the numbers of C_2H_4O subunits in the PEG chain.

50. Defendants have been and is now directly and indirectly infringing one or more claims of the ‘190 Patent, in this judicial District and elsewhere in the United States.

51. For example, Defendants directly infringe the ‘190 Patent, including but not limited to claim 1, by offering to sell the QuSomes Products, according to the claims of the ‘190 Patent.

52. QuSomes Products include active compounds according to claim 1 of the ‘190 Patent.

53. Defendants also directly and indirectly infringe the ‘190 Patent, including but not limited to claim 1, to the extent Defendants may also be making, using, selling, or importing QuSomes Products.

54. Defendants have committed these acts of infringement without license or authorization.

55. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the '190 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

56. As a result of Defendants' infringement of the '190 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 7,150,883

57. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

58. On December 19, 2006, the United States Patent and Trademark Office issued the '883 Patent for inventions relating to self forming, thermodynamically stable liposomes and their applications. The embodiment of claim 1 recites a composition for use in preparing a liposomal formulation of a therapeutic agent, the composition comprising: one or more lipids where the total lipids have a P_a between about 0.84 and 0.88 and a P_v between about 0.88 and 0.93, where P_a is the packing parameter with respect to surface and P_v is the packing parameter with respect to volume, where one or more of the lipids is a diacylglycerol-PEG having a melting point below about 40 degrees C and also having acyl chains greater than 14 carbons in length, and the therapeutic agent.

59. Defendants have been and is now directly and indirectly infringing one or more claims of the '883 Patent, in this judicial District and elsewhere in the United States.

60. For example, Defendants directly and indirectly infringe the '883 Patent, including but not limited to claim 1, by offering to sell the Infacin Products, according to the claims of the '883 Patent as described herein.

61. Defendants also directly and indirectly infringe the ‘883 Patent, including but not limited to claim 1, to the extent Defendants may also be making, using, selling, or importing Inflacin Products.

62. Defendants have committed these acts of infringement without license or authorization.

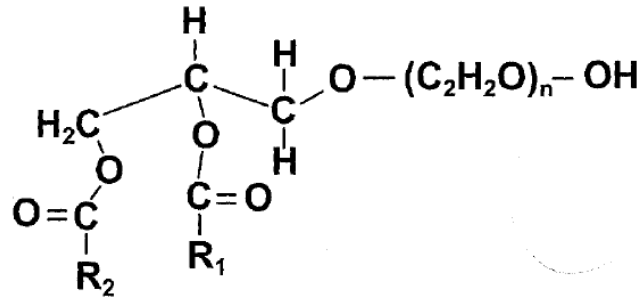
63. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the ‘833 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

64. As a result of Defendants’ infringement of the ‘883 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 6,495,596

65. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

66. On December 17, 2002, the United States Patent and Trademark Office issued the ‘596 Patent for inventions relating to compounds and methods for inhibition of phospholipase A2 and cyclooxygenase-2. The embodiment of claim 16 recites a lipid compound represented by the formula



wherein R_1 is a long chain fatty acid, R_2 is a long chain fatty acid between 11 and 25 carbons in length, and wherein the variable “n” is an integer between 11 and 46, and wherein said compound is characterized by the ability to inhibit biological activity of phospholipase A_2 .

67. Defendants have been and is now directly and indirectly infringing one or more claims of the ‘596 Patent, in this judicial District and elsewhere in the United States.

68. For example, Defendants directly and indirectly infringe the ‘596 Patent, including but not limited to claim 16, by offering to sell the Infacin Products, according to the claims of the ‘596 Patent as described herein.

69. Defendants also directly and indirectly infringe the ‘596 Patent, including but not limited to claim 16, to the extent Defendants may also be making, using, selling, or importing Infacin Products.

70. Defendants have committed these acts of infringement without license or authorization.

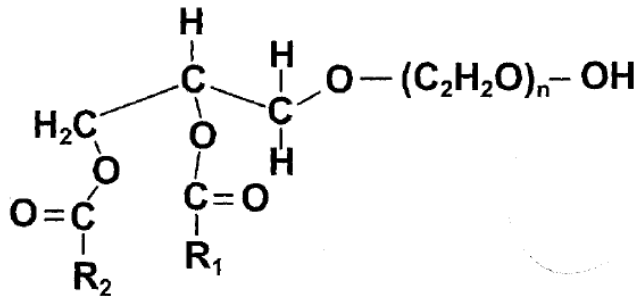
71. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the ‘596 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

72. As a result of Defendants’ infringement of the ‘596 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 6,998,421

73. Plaintiff incorporates by reference each of the allegations in the foregoing paragraphs, and further alleges as follows:

74. On February 14, 2006, the United States Patent and Trademark Office issued the ‘421 Patent for inventions relating to compounds and methods for inhibition of phospholipase A2 and cyclooxygenase-2. The embodiment of claim 1 recites a lipid compound represented by



the formula

wherein R₁ is a long chain fatty acid, R₂ is a long chain fatty acid between 11 and 25 carbons in length, and wherein the variable “n” is an integer between 11 and 46, and wherein said compound is characterized by the ability to inhibit biological activity of phospholipase A₂.

75. Defendants have been and is now directly and indirectly infringing one or more claims of the ‘421 Patent, in this judicial District and elsewhere in the United States.

76. For example, Defendants directly infringe the ‘421 Patent, including but not limited to claim 1, by offering to sell the Infacin Products, according to the claims of the ‘421 Patent.

77. Defendants also directly and indirectly infringe the '421 Patent, including but not limited to claim 1, to the extent Defendants may also be making, using, selling, or importing Inflacin Products.

78. Defendants have committed these acts of infringement without license or authorization.

79. Defendants have injured BioZone and is liable to BioZone for direct and indirect infringement of the claims of the '421 Patent pursuant to 35 U.S.C. § 271(a), (b), and (c).

80. As a result of Defendants' infringement of the '421 Patent, BioZone has suffered harm and seeks injunctive relief and monetary damages in an amount adequate to compensate for infringement, but in no event less than a reasonable royalty, together with interest and costs as fixed by the Court.

PRAAYER FOR RELIEF

Plaintiff respectfully requests the following relief from this Court:

- A. That Defendants have directly and indirectly infringed the Patents-in-Suit;
- B. That Defendants be ordered to pay damages to BioZone, together with costs, expenses, pre-judgment interest and post-judgment interest as allowed by law;
- C. That Defendants' infringement has been willful, entitling BioZone to treble damages under 35 U.S.C. § 284;
- D. That the Court enter a preliminary and permanent injunction against Defendants' infringement of the Patents-in-Suit;
- E. That the Court find this case to be exceptional under 35 U.S.C. § 285 and that BioZone is entitled to its fees and costs;
- F. That the Court enter judgment against Defendants, and in favor of BioZone in all

respects; and

G. For any such other and further relief as the Court deems just and equitable.

JURY TRIAL DEMANDED

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, BioZone requests a trial by jury of any issues so triable by right.

Respectfully submitted,

Dated: New York, New York
June 5, 2018

**INGRAM YUZEK GAINEN CARROLL
& BERTOLOTTI, LLP**

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